

JUN 26 2001



K011542

**510(k) Summary**

**Submitter Information:**

Specialty UltraVision, Inc.  
307 Orchard City Drive, Suite 100  
Campbell, CA 95008

**Contact Person:**

Garold L. Edwards, O.D., F.A.A.O.  
Vice President, Technical Affairs

**Telephone:**

(408) 341-0700

**Fax:**

(408) 341-0717

**Date Prepared:**

May 14, 2001

**Device Name:**

**Common Name:**

ocufilcon D

**Trade/Proprietary Names:**

**Specialty D-UV** (ocufilcon D) Soft  
(Hydrophilic) Contact Lens for Daily Wear

**Specialty D-UV Multifocal** (ocufilcon D) Soft (Hydrophilic)  
Contact Lens for Daily Wear

**Specialty D-UV Toric** (ocufilcon D) Soft (Hydrophilic)  
Contact Lens for Daily Wear

**Classification Name:**

Soft (Hydrophilic) Contact Lens

**Device Classification:**

Class II (21 CFR 886.5925)

**Predicate Devices:**

The Biomedics 55 (ocufilcon D) UV Blocking Soft (Hydrophilic) Contact Lens was selected as the predicate devices because of its similarities in intended use (daily wear), physical characteristics, and material type (FDA Group 4; high water, ionic). Biomedics 55 (ocufilcon D) UV Blocking Soft (Hydrophilic) Contact Lens for Daily Wear was cleared for marketing on January 21, 1999 under K984046.

**Description of Devices:**

The Specialty D-UV, Specialty D-UV Multifocal, and Specialty D-UV Toric (ocufilcon D) Daily Wear Contact Lenses are hemispheric flexible shells that cover the cornea and a portion of the adjacent sclera. The Specialty D-UV Contact Lens is available in a single vision lens design, the Specialty D-UV Multifocal Contact Lens is available in an aspheric lens design, and the Specialty D-UV Toric Contact Lens is available in a back or front surface toric design. The lens material (ocufilcon D) is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) and methacrylic acid cross-linked with ethyleneglycol dimethacrylate (45.0%) and water (55.0%). An UV-absorbing compound has been incorporated into the lens polymer. All lenses are tinted using the color additive Reactive Blue #19.

## Comparison to Predicate Device

PARAMETER	Specialty D-UV, Specialty D-UV Multifocal, and Specialty D-UV Toric (ocufilcon D) Soft (Hydrophilic) Contact Lenses for Daily Wear	Biomedics 55 (ocufilcon D) UV Blocking Soft (Hydrophilic) Contact Lenses for Daily Wear
Submission number		K984046
Material	ocufilcon D	ocufilcon D
Material classification	Hydrophilic Lens Group 4	Hydrophilic Lens Group 4
Indication for use	myopia, hyperopia, presbyopia and astigmatism	myopia, hyperopia, and astigmatism
Water content	55%	55%
Visible light transmittance	98.3%	98.5%
UV transmittance	< 10%	<10%
Dk (35° C)	$18.9 \times 10^{-11}$	$18.9 \times 10^{-11}$
Powers	+20.00 to -20.00 Diopters	+20.00 to -20.00 Diopters
Color	blue visibility	visibility tinted
Refractive index	1.42	1.42
Specific gravity	1.06	1.06
Method of manufacture	Molded	Molded

### Indications for Use:

The **Specialty D-UV (ocufilcon D) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **Specialty D-UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **Specialty D-UV Toric (ocufilcon D) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 5.00 Diopters.

The lenses may be disinfected using chemical (not heat) or hydrogen peroxide disinfecting systems. Eyecare practitioners may prescribe the lenses for daily wear and/or frequent replacement. When prescribed for a Frequent Replacement Program, the lenses may be disinfected using chemical (not heat) or hydrogen peroxide disinfecting systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Garold L. Edwards, O.D., F.A.A.O.  
Vice President, Technical Affairs  
Specialty UltraVision, Inc.  
307 Orchard Drive  
Suite 100  
Campbell, CA 95008

Re: K011542

Trade Name: Specialty D-UV (ocufilcon D) Soft (Hydrophilic) Contact Lens for Daily Wear,  
Specialty D-UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lens for Daily Wear,  
Specialty D-UV Toric (ocufilcon D) Soft (Hydrophilic) Contact Lens for Daily Wear  
Regulation Number: 886.5925  
Regulatory Class: II  
Product Code: LPL  
Dated: May 17, 2001  
Received: May 18, 2001

Dear Dr. Edwards:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "A. Ralph Rosenthal".

A. Ralph Rosenthal, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

K011542

## INDICATIONS STATEMENT

### Device Names:

**Specialty D-UV** (ocufilcon D) Soft (Hydrophilic) Contact Lens for Daily Wear

**Specialty D-UV Multifocal** (ocufilcon D) Soft (Hydrophilic) Contact Lens for Daily Wear

**Specialty D-UV Toric** (ocufilcon D) Soft (Hydrophilic) Contact Lens for Daily Wear

### Indications for Use:

The **Specialty D-UV (ocufilcon D) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **Specialty D-UV Multifocal (ocufilcon D) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) and presbyopia in aphakic and not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 2.00 Diopters that does not interfere with visual acuity.

The **Specialty D-UV Toric (ocufilcon D) Soft (Hydrophilic) Contact Lens** is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia and astigmatism) in aphakic or not aphakic persons with non-diseased eyes that may exhibit refractive and/or corneal astigmatism up to 5.00 Diopters.

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**(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-the-Counter Use ☐



Daniel W.C. Brown, Ph.D.  
(Division Sign-Off)

Division of Ophthalmic Devices

510(k) Number K011542